CONSTITUENT DELIVERY SYSTEM

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Background of the Invention

In delivery of items, for example medicine or pharmaceuticals or food stuffs, especially when the items are shipped long distances, in order to ensure a long shelf life of the items, portions are often separated into constituent parts and then recombined just prior to use, for example with medicines such as antibiotics, portions are freeze dried and shipped separately from a sterile liquid component whereupon the liquid portion of the container is sterilized and the dried ingredients are added thereto and mixed and the liquid thus produced is then available for use with a syringe, for injecting into a patient, for example, or for consuming orally if that is the appropriate mode of consumption.

An alternative method of employing such separate constituents which are later mixed is to have both the freeze dried component and the liquid component in separate sterile containers (for example, the liquid component may be in a prefilled syringe and the freeze dried component in a vial which includes a syringe-penetrable top). The vial top is sterilized through use of an alcohol swab, for example, and the syringe is caused to penetrate the top thereof so as to enable injection of the liquid into the vial. The syringe is then suitably withdrawn and the liquid and freeze dried component are mixed to create a well dispersed suspension or until the freeze dried component dissolves whereupon the vial top may again be sterilized through use of an alcohol swab and the liquid pharmaceutical then be withdrawn in the appropriate amount with the syringe, for injection into the patient.

Such systems are at times less than desirable, since the separate shipping or packaging of the various components is prone to situations where one constituent is shipped and separated from the other constituent, resulting in difficulties in keeping the two constituents together. Further, the chance of contamination or infection of the ingredients is greater, since the number of steps where sterility must be maintained is increased, for example, the syringe must be maintained sterile, the contents of the syringe must be maintained in a sterile condition, the freeze dried component must be maintained in a sterile condition and the external surfaces of the containers which may contact various parts of the syringe or the like must also be maintained or made sterile, increasing the chance of contamination. Another drawback arises when the liquid portion is typically provided in bulk and must be measured at the time of reconstituting with sterile measuring. Such remixing may be difficult in field locations which may not have access to sterile conditions.

Summary of the Invention

According to the present invention, a system of at least two constituents is provided in a unitary container wherein a liquid constituent, for example, is contained within a vial which may take the shape of a cup and an inner lid portion seals the liquid constituent within its container. An outer lid is also provided with a space defined between the inner and outer lid wherein the other constituent or constituents are contained within the space therebetween. In use, the other constituent is caused to penetrate the inner lid so as to combine with the liquid ingredient, while the

outer lid is maintained in its sealed state. The constituents are still maintained sterile within the vial or cup. Mixing then occurs whereupon the outer lid may be removed, or alternatively, may be sterilized with an alcohol wipe and a syringe inserted therein.

It is an object of the invention to provide an improved delivery system and method for providing multipart constituents.

It is a further object of the present invention to provide an improved system for providing pharmaceuticals with separated portions while enabling reconstituting the portions in a sterile environment.

It is an object of the present invention to provide an improved method and system for enabling premixing of constituents in premeasured portions prior to use.

<u>Brief Description of the Drawings</u>

FIG. 1 is a cross sectional view of a container according to the present invention for providing two constituents;

FIG. 2 is a cross sectional view of the container of FIG. 1 after the ingredients are combined;

FIG. 3 is a view of the container of FIG. 2 illustrating removal of the now mixed components via use of a syringe;

FIG. 4 is a view of the capsule portion of the container of FIG. 1; ~~and~~

FIG. 5 is a view of an alternative capsule portion

Detailed Description

Referring now to FIG. 1, a container 10 in accordance with the present invention comprises a cup-like container 12, which suitably is made of plastic wherein a liquid 14 is contained within the cup. In the illustrated embodiment, the liquid comprises 4-9 ccs in volume. The interior bottom of the cup defines a well 16 therein with inwardly sloping walls so as to ensure that the center 18 of the well is the lowest most point within the interior of the cup or vial 12. The interior of the cup may comprise solid portions 20 which assist in defining the shape of the well.

Near the top of the cup is provided an inner lid 22 which substantially seals the interior of the liquid containing chamber and an outer lid 24 which is also secured to the cup 12 or to the top of bottom lid 22. A central cavity 26 is suitably defined between the top lid 24 and the lower lid 22 wherein a capsule member 28 is positioned within the chamber. The capsule may contain a medicine or freeze dried constituent of an antibiotic, for example, 30 therewithin. In this state, the two constituents 14 and 30 are maintained separate from each other, but are sealed to the outside world so as to ensure sterility. The region of top lid 24 above capsule 28 may suitably comprise a rubber stopper portion 32 of the type employed in vials wherein a syringe may be inserted therein as necessary.

Referring now to FIG. 4, the structure of capsule portion 28 may be observed. The capsule may suitably be of plastic or glass or any other suitable material and includes sharp edge portions 34 and sealed top portion 36, which may also

include a rubberized stopper of the type normally employed in conjunction with vials adapted for use with syringes. The constituent is suitably confined within the capsule, but the bottom of the capsule remains opened. The bottom lid is thus relied upon to keep the medicine within the capsule, since the bottom lid would thus provide the bottom sealing portion to capsule 28.

Referring now to FIG. 2, in use, in order to mix the two constituents, top lid 24 is pushed downwardly in the direction of arrow 38 of FIG. 2 whereupon the sharp edge portions 34 of the capsule puncture the bottom lid. Since the bottom lid is suitably designed to be so punctured, the constituent 30 is released into the liquid 14 whereupon the two are mixed through vigorous shaking if appropriate. Note that the top lid seal has not been broken, so the interior of the cup 12 remains sterile or otherwise unopen to the outside atmosphere.

Referring now to FIG. 3, to retrieve the now mixed ingredients 40, which is the combination of the constituent 30 and 14, a syringe 42 is inserted through region 32 which suitably comprises a rubber stopper or the like as typically employed with syringe receiving vials (suitably after the top thereof is cleansed with an alcohol swipe or the like). The needle 44 of the syringe suitably extends down to the bottom 18 of well 16 so as to enable withdrawal of the maximum amount of the liquid constituent 40 as possible without excessive waste.

It should be noted that the container and its ingredients may be so measured as to either provide single dosage or multiple dose as desired. As an example, ingredients 14 and 30 may comprise a

liquid constituent and a freeze dried antibiotic, vitamin components, or other pharmaceuticals. Also, the items together may comprise certain foodstuffs or the like.

Referring to FIG. 5, an alternative embodiment employs a capsule 28' which is suitably made of an inert ingredient that dissolves in the liquid, such as a gelatin type capsule typically used in the delivery of pharmaceuticals or vitamins. In this embodiment, the ingredient 30 is contained within the capsule and bottom lid portion 22 is sufficiently thin so as to enable the capsule 28' to penetrate through the bottom lid when the top lid is pressed downwardly in the direction of arrow 38 (FIG. 2). The capsule 28' then falls into the liquid portion 14 and suitably dissolves to release ingredient 30 to the liquid for subsequent mixing.

The lid portion 24 is also provided in an alternative embodiment in a deformable plastic which once pressed downwardly retains its deformed shape or becomes discolored so as to enable a determination to be made whether the capsule portion has been depressed into the liquid portion. Thus, on quick inspection, it is possible to determine whether the cup is a fresh unmixed vial or whether it has been previously mixed either intentionally or through damage during shipping.

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Accordingly, the present invention provides an improved delivery system and method for providing separate constituents, suitably food or pharmaceutical ingredients, enabling longer shelf life while maintaining sterile conditions and enabling sterile mixing in the field.

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